



Used in Lieu of PTO/SB/08A/B
(Based on PTO 01-08 version)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	1	of	10	Attorney Docket Number	BBI-8187RCE

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1*	US-5,231,024	07-27-1993	Moeller et al.	
	A2*	US-5,654,407	08-05-1997	Boyle et al.	
	A3*	US-5,795,967	08-18-1998	Aggarwal et al.	
	A4*	US-5,859,205	01-12-1999	Adair et al.	
	A5*	US-5,877,293	03-02-1999	Adair et al.	
	A6*	US-5,929,212	07-27-1999	Jolliffe et al.	
	A7*	US-5,994,510	11-30-1999	Adair et al.	
	A8*	US-6,090,382	07-18-2000	Salfeld et al.	
	A9*	US-6,214,870	04-10-2001	McClure et al.	
	A10*	US-6,235,281	05-22-2001	Stenzel et al.	
	A11*	US-6,258,562	07-10-2001	Salfeld et al.	
	A12*	US-6,270,766	08-07-2001	Feldman et al.	
	A13*	US-20030049725-A1	03-13-2003	Heavner, George et al.	
	A14*	US-20030092059-A1	05-15-2003	Salfeld et al.	
	A15*	US-20030219438-A1	11-27-2003	Salfeld et al.	
	A16*	US-20030235585-A1	12-25-2003	Fischkoff et al.	
	A17*	US-20040033228-A1	02-19-2004	Krause et al.	
	A18*	US-20040120952-A1	06-24-2004	Knight, David M. et al.	
	A19*	US-20040126372-A1	07-01-2004	Banerjee et al.	
	A20*	US-20040131614-A1	07-08-2004	Banerjee et al.	
	A21*	US-20040136989-A1	07-15-2004	Banerjee et al.	
	A22*	US-20040136990-A1	07-15-2004	Banerjee et al.	
	A23*	US-20040151722-A1	08-05-2004	Banerjee et al.	
	A24*	US-20040166111-A1	08-26-2004	Kaymakcalan et al.	
	A25*	US-20040219142-A1	11-04-2004	Banerjee et al.	
	A26*	US-20050123541-A1	06-09-2005	Heavner, George et al.	
	A27*	US-20050249735-A1	11-10-2005	Le, Junming et al.	
	A28*	US-20060009385-A1	01-12-2006	Hoffman et al.	
	A29*	US-20060018907-A1	01-26-2006	Le, Junming et al.	
	A30*	US-20060024293-A1	02-02-2006	Salfeld, Jochen et al.	
	A31*	US-20060153846-A1	07-13-2006	Krause et al.	
	A32*	US-20060246073-A1	11-02-2006	Knight, David et al.	
	A33*	US-20070003548-A1	01-04-2007	Heavner, George et al.	
	A34*	US-7223394-B2	05-29-2007	Salfeld, Jochen G. et al.	
	A35*	US-7250165-B2	07-31-2007	Heavner, George et al.	
	A36*	US-20070196373-A1	08-23-2007	Le, Junming et al.	
	A37*	US-20070249813-A1	10-25-2007	Salfeld, Jochen G. et al.	
	A38*	US-20070298040-A1	12-27-2007	Le, Junming et al.	
	A39*	US-20080025976-A1	01-31-2008	Le, Junming et al.	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	2	of	10	Attorney Docket Number	BBI-8187RCE

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	B1	EP-0101681-B1	03-07-1984	The Rockefeller University		
	B2	EP-0186833-B1	07-09-1986	Yeda Research and Development Company Limited		
	B3	EP-0212489-B1	03-04-1987	The Rockefeller University		
	B4	EP-0351789-B1	01-24-1990	Chiron Corporation		
	B5	EP-0366043-B1	05-02-1990	Otsuka Pharmaceutical Co., Ltd.		
	B6	WO-91/02078-A1	02-21-1991	Peptide Technology, Ltd.		
	B7	EP-0492448-B1	07-01-1992	Pharmacia & Upjohn S.p.A.		
	B8	WO-92/11383-A1	07-09-1992	Celltech Limited		
	B9	WO-92/16553-A1	10-01-1992	New York University et al.		
	B10	WO-93/06213-A1	04-01-1993	Medical Research Council et al.		
	B11	WO-93/11793-A1	06-24-1993	Schering Corporation		
	B12	EP-0614984-B1	09-14-1994	Bayer Corporation		
	B13	GB-2279077	12-21-1994	Celltech Limited		
	B14	WO-94/29347-A1	12-22-1994	Therapeutic Antibodies, Inc.		
	B15	EP-0659766-A1	06-28-1995	Schering-Plough		
	B16	WO-95/23813-A1	09-08-1995	Merck & Co., Inc.		
	B17	WO-98/05357-A1	02-12-1998	The Kennedy Institute of Rheumatology		
	B18	WO-01/00229-A1	01-04-2001	Pharmacia Corporation		
	B19	WO-02/100330-A3	12-19-2002	Abbott Biotechnology Ltd.		
	B20	WO-06/041970-A2	04-20-2006	Abbott Biotechnology Ltd.		
	B21	WO-04/092448-A2	10-28-2004	Newmont USA Limited		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Abraham, Edward, et al., "Efficacy and Safety of Monoclonal Antibody to Human Tumor Necrosis Factor α in Patients with Sepsis Syndrome," <i>JAMA</i> , Vol. 273(12):934-941 (1995)	
	C2	Abraham, E., "Why immunomodulatory therapies have not worked in sepsis," <i>Intensive Care Med.</i> , Vol. 25:556-566 (1999)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	3	of	10	Attorney Docket Number	BBI-8187RCE

C3	Awni, Walid M. et al., "Steady-State Pharmacokinetics (PK) of Adalimumab (HUMIRA™, Abbott) Following 40 mg Subcutaneous (sc) Injection Every Other Week (eow) in Rheumatoid Arthritis (RA) Patients with and without Methotrexate (MTX) Background Therapy," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S140 (2003)	
C4	BARBUTO, J.A.M. et al. "Production of Neutralizing Antibodies to Tumor Necrosis Factor by Human Tumor-Infiltrating B Lymphocytes" <i>Proc. Am. Assoc. Cancer Res.</i> , 34:487, Abstr. 2904 (1993)	
C5	Barrera, P. et al., "Drug survival, efficacy and toxicity of monotherapy with a fully human anti-tumour necrosis with a fully human anti-tumour necrosis factor- α antibody compared with methotrexate in long-standing rheumatoid arthritis," <i>Rheumatology</i> , Vol. 41:430-439 (2002)	
C6	Barrera, Pilar et al., "Effect of a Fully Human Anti-TNF α Monoclonal Antibody on the Local and Systemic Expression of TNF α and IL-1 β ," <i>Arthritis Rheum.</i> , Vol. 42(9 Suppl.):S75 (1999)	
C7	BENDTZEN, K. et al. "Auto-antibodies to IL-1 α and TNF α in Normal Individuals and in Infectious and Immunoinflammatory Disorders" <i>The Physiological and Pathological Effects of Cytokines</i> , 447-52 (1990)	
C8	Boekstegers, P., et al., "Repeated administration of a F(ab') ₂ fragment of an anti-tumor necrosis factor alpha monoclonal antibody in patients with severe sepsis: effects on the cardiovascular system and cytokine levels," <i>Shock</i> , Vol. 1(4):237-245 (1994)	
C9	Bombardier, C. et al., "Pattern of DMARD use in a North American Cohort of Patients with Early Rheumatoid Arthritis (RA) (SONORA)," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S344 (2002)	
C10	BOYLE, P. et al. "A Novel Monoclonal Human IgM Autoantibody which Binds Recombinant Human and Mouse Tumor Necrosis Factor- α " <i>Cell. Immunol.</i> , 152:556-68 (1993)	
C11	BOYLE, P. et al. "The B5 Monoclonal Human Autoantibody Binds to Cell Surface TNF α on Human Lymphoid Cells and Cell Lines and Appears to Recognize a Novel Epitope" <i>Cell. Immunol.</i> , 152:569-81 (1993)	
C12	Breedveld, F.C. et al., "Sustained Efficacy Over 4 Years with Adalimumab in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):169 (2003)	
C13	Breedveld, Ferdinand C. et al., "Sustained Efficacy over 5 Years with Adalimumab (HUMIRA™) in Patients with Active Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S118 (2003)	
C14	Breedveld, F. et al., "The Long-term Efficacy and Safety of Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in the Treatment of Rheumatoid Arthritis: Results of a 2-Year Study," <i>JCR: Journal of Clinical Rheumatology</i> , Vol. 8(Suppl. 3):S46 (2002)	
C15	Breedveld, F.C. et al., "The Fully Human Anti-TNF Antibody Adalimumab (D2E7) in Combination with Methotrexate (MTX) in the Treatment of Active Rheumatoid Arthritis: Results of a 2-Year Study," <i>Presented at: The Annual Meeting of the European League Against Rheumatism (EULAR), Prague, Czech Republic, June 2001</i>	
C16	Brekke, Ole Henrik et al., "Therapeutic Antibodies for Human Diseases at the Dawn of the Twenty-first Century," <i>Nature</i> , Vol. 2:52-62 (2002)	
C17	Burmester, G.R. et al., "Long-Term Efficacy and Safety of Adalimumab (D2E7) Monotherapy in Patients With DMARD-Refractory Rheumatoid Arthritis - Results From a 2-Year Study," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S537 (2002)	
C18	Burmester, G.R. et al., "Sustained Efficacy of Adalimumab Monotherapy for More than Four Years in DMARD-Refractory RA," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):192-3 (2003)	
C19	Case, John P., "Old and New Drugs Used in Rheumatoid Arthritis: A Historical Perspective," <i>American Journal of Therapeutics</i> , Vol. 8:163-179 (2001)	
C20	Chartash, E.K. et al., "Adalimumab Improves Fatigue in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):349 (2003)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	4	of	10	Attorney Docket Number	BBI-8187RCE

C21	CHOW, A.W. <i>et al.</i> "Effect of monoclonal antibody on human tumor necrosis factor (TNF MAb) on TNF α , IL-1 β , and IL-6 levels in patients with sepsis syndrome" <i>Clinical Research</i> , 42:2 299A (1994)
C22	Cohen, Jonathan, <i>et al.</i> , "Intersept: An international, multicenter, placebo-controlled trial of monoclonal antibody to human tumor necrosis factor- α in patients with sepsis," <i>Crit Care Med</i> , Vol. 24(9):1431-1440 (1996)
C23	Colman, P.M., "Effects of amino acid sequence changes on antibody-antigen interactions," <i>Research in Immunology</i> , Vol. 145(1):33-36 (1994)
C24	COX, J.P.L. <i>et al.</i> "A directory of human germ-line V κ segments reveals a strong bias in their usage" <i>Eur. J. Immunol.</i> , 24(2):827-36 (1994)
C25	den Broeder, A.A. <i>et al.</i> , "The Effect of D2E7, a new human anti-TNF α monoclonal antibody, on the oxidative burst of PMN in patients with RA," <i>Arthritis and Rheumatism</i> , Vol. 41(9):S57 (1998)
C26	den Broeder, Alfons <i>et al.</i> , "A Single Dose, Placebo Controlled Study of the Fully Human Anti-Tumor Necrosis Factor- α Antibody Adalimumab (D2E7) in Patients with Rheumatoid Arthritis," <i>The Journal of Rheumatology</i> , Vol. 29(11):2288-2298 (2002)
C27	den Broeder, A.A. <i>et al.</i> , "Long term anti-tumour necrosis factor α monotherapy in rheumatoid arthritis: effect on radiological course and prognostic value of markers of cartilage turnover and endothelial activation," <i>Ann. Rheum. Dis.</i> , Vol. 61:311-318 (2002)
C28	Department of Surgery, University of Toronto, Annual Report (1998-1999)
C29	Egan, L.J. <i>et al.</i> "A randomized, single-blind, pharmacokinetic and doseresponse study of subcutaneous methotrexate, 15 and 25 MG/week, for refractory ulcerative colitis and Crohn's Disease," <i>Gastroenterology</i> , Vol. 114(4):G3978 (1998)
C30	ELLIOTT, M.J. <i>et al.</i> "Treatment of rheumatoid arthritis with chimeric monoclonal antibodies to tumor necrosis factor α " <i>Arthritis & Rheumatism</i> , 36(12):1681-90 (1993)
C31	Emery, Paul <i>et al.</i> , "Changes in PRO-MMP-1 in Relation to Standard Measures of Disease Activity Over a 6 Month Treatment Period with Adalimumab (D2E7) in Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 44(9):S215 (2001)
C32	Feldmann, Marc <i>et al.</i> , "Anti-TNF α Therapy of Rheumatoid Arthritis: What Have We Learned," <i>Annu. Rev. Immunol.</i> , Vol. 19:163-196 (2001)
C33	Figini, Mariangela <i>et al.</i> , "In Vitro Assembly of Repertoires of Antibody Chains on the Surface of Phage by Renaturation," <i>J. Mol. Biol.</i> , Vol. 239:68-78 (1994)
C34	FOMSGAARD, A. <i>et al.</i> "Auto-antibodies to Tumour Necrosis Factor α in Healthy Humans and Patients with Inflammatory Diseases and Gram-Negative Bacterial Infections" <i>Scand. J. Immunol.</i> , 30:219-23 (1989)
C35	Foote, Jefferson <i>et al.</i> , "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops," <i>J. Mol. Biol.</i> , Vol. 224:487-499 (1992)
C36	Furst, D.E. <i>et al.</i> , "Safety and Efficacy of Adalimumab (D2E7), a Fully Human Anti-TNF- α Monoclonal Antibody, Given in Combination with Standard Antirheumatic Therapy: Safety Trial of Adalimumab in Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S572 (2002)
C37	Furst, Daniel E. <i>et al.</i> , "Adalimumab, a Fully Human Anti-Tumor Necrosis Factor- α Monoclonal Antibody, and Concomitant Standard Antirheumatic Therapy for the Treatment of Rheumatoid Arthritis: Results of STAR (Safety Trial of Adalimumab in Rheumatoid Arthritis)," <i>The Journal of Rheumatology</i> , Vol. 30(12):2563-2571 (2003)
C38	Furst, Daniel <i>et al.</i> , "TNF Blockade by the Fully Human Monoclonal Antibody Adalimumab (D2E7), in the Armada Trial Results in Decreases in Serum Matrix Metalloproteinase (MMP) Levels Along with Impressive Clinical Improvement in Refractory RA Patients," <i>Arthritis Rheum.</i> , Vol. 44(9 Suppl.):S215 (2001)
C39	Goto, Daisuke <i>et al.</i> , "Adalimumab," Medline AC NLM12510366 (2002)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	5	of	10	Attorney Docket Number	BBI-8187RCE

C40	Goto, Daisuke et al., "Adalimumab," <i>Nippon Rinsho</i> , 60(12): 2384-2389 (2002)	
C41	Granneman, Richard G. et al., "Pharmacokinetic/Pharmacodynamic (PK/PD) Relationships of Adalimumab (HUMIRA™, Abbott) in Rheumatoid Arthritis (RA) Patients during Phase II/III Clinical Trials," <i>Arthritis. Rheum.</i> , Vol. 48(Suppl. 9):S140 (2003)	
C42	GRIFFITHS, A.D. et al. "Human anti-self antibodies with high specificity from phage display libraries" <i>The EMBO J.</i> , 12(2):725-34 (1993)	
C43	Hawkins, Robert E. et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation," <i>J. Mol. Biol.</i> , Vol. 226:889-896 (1992)	
C44	Holler, et al., "Modulation of Acute Graft-Versus-Host Disease After Allogeneic Bone Marrow Transplantation by Tumor Necrosis Factor α (TNF α) Release in the Course of Pretransplant Conditioning: Role of Conditioning Regimens and Prophylactic Application of a Monoclonal Antibody Neutralizing Human TNF α (MAK 195F)," <i>Blood</i> , Vol. 86(3):890-899 (1995)	
C45	Holliger, Philipp et al., "Engineered antibody fragments and the rise of single domains," <i>Nature Biotechnology</i> , Vol. 23(9):1126-1136 (2005)	
C46	Hoogenboom, Hennie R. et al., "Converting rodent into human antibodies by guided selection," <i>Antibody Engineering</i> , Oxford University Press, Chpt. 8, pgs. 169-185 (1996)	
C47	HUSE, W.D. et al. "Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda" <i>Science</i> , 246:1275-81 (1989)	
C48	Janeway, Charles A., Jr., "The structure of a typical antibody molecule," <i>Immunobiology</i> , Vol. 5, Garland Publishing (2001)	
C49	Janeway, Charles A., Jr., "The protein products of MHC class I and class II genes are highly polymorphic," <i>Immunobiology</i> , 3 rd Edition, Garland Publishing, pgs. 4:24-4:30 (1997)	
C50	Jespers, Laurent S. et al., "Guiding the Selection of Human Antibodies from Phage Display Repertoires to a Single Epitope of an Antigen," <i>BioTechnology</i> , Vol. 12:899-903 (1994)	
C51	Kanakoudi-Tsakalidou, F. et al., "Influenza vaccination in children with chronic rheumatic diseases and long-term immunosuppressive therapy," <i>Clinical and Experimental Rheumatology</i> , Vol. 19:589-594 (2001)	
C52	Kavanaugh, A.F. et al., "The Armada Trial: 12-Month Efficacy and Safety of Combination Therapy with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, and Methotrexate (MTX) in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S168 (2002)	
C53	Kavanaugh, A. et al., "Immune Response is Not Affected by Adalimumab Therapy," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):169 (2003)	
C54	Kavanaugh, Arthur F. et al., "Treatment with Adalimumab (D2E7) does not Affect Normal Immune Responsiveness," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S132 (2002)	
C55	Kaymakcalan, Z. et al., "Comparison of Adalimumab (D2E7), Infliximab, and Etanercept in the Prevention of Polyarthritis in the Transgene Murine Model of Rheumatoid Arthritis," <i>Arthritis, Rheum.</i> , Vol. 46(9 Suppl.):S304 (2002)	
C56	Kempni, Joachim, "Update on D2E7: a fully human anti-tumour necrosis factor α monoclonal antibody," <i>Ann. Rheum. Dis.</i> , Vol. 59(Suppl. 1):144-145 (2000)	
C57	Kempni, Joachim, "Preliminary Results of early clinical trials with the fully human anti-TNF α monoclonal antibody D2E7," <i>Ann. Rheum. Dis.</i> , Vol. 58(Suppl. 1):170-172 (1999)	
C58	Keystone, E. et al., "Efficacy and Safety of Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in MTX Partial Responders: Results of the 24-week ARMADA Trial," <i>JCR: Journal of Clinical Rheumatology</i> , Vol. 8(3):S69 (2002)	
C59	Keystone, Edward et al., "The Armada Trial: A Double-Blind Placebo Controlled Trial of the Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), in Patients with Active RA on Methotrexate (MTX)," <i>Arthritis & Rheumatism</i> , Vol. 44(9):S213 (2001)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	6	of	10	Attorney Docket Number	BBI-8187RCE

C60	Keystone, E. et al., "Adalimumab Inhibits the Progression of Structural Joint Damage in Patients with Active RA," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):64-5 (2003)	
C61	Keystone, Edward et al., "Sustained Radiographic Inhibition with Adalimumab (HUMIRA™) over 2 years in Patients with Long Standing Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S315 (2003)	
C62	Keystone, E. et al., "The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)," <i>Presented at the Annual Meeting of the European League Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, (2001)</i>	
C63	Keystone, E.C. et al., "Subgroup Analysis of Radiographic Progression in RA Patients with Moderate Disease Treated with Adalimumab (HUMIRA®)," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):169 (2003)	
C64	Kremer, Joel M., "Rational Use of New and Existing Disease-Modifying Agents in Rheumatoid Arthritis," <i>Ann. Intern. Med.</i> , Vol. 134:695-706 (2001)	
C65	LERNER, R.A. et al. "Antibodies without immunization" <i>Science</i> , 258:1313-14 (1992)	
C66	LEUSCH, H-G. et al. "Failure to demonstrate TNF α -specific autoantibodies in human sera by ELISA and Western blot" <i>J. Immunol. Methods</i> , 139:145-47 (1991)	
C67	LEWIS et al. "Use of alanine scanning mutagenesis to improve the affinity of an anti gp120 (HIV) antibody." <i>J. Cell. Biochem.</i> , 18D:215 (1994)	
C68	Low, Nigel M., thesis extract, Cambridge University (1996)	
C69	Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i> , Vol. 260:359-368 (1996)	
C70	Machold, Klaus P. et al., "Adalimumab - a new TNF- α antibody for treatment of inflammatory joint disease," <i>Expert Opin. Biol. Ther.</i> , Vol. 3(2):351-360 (2003)	
C71	MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" <i>J. Mol. Biol.</i> 222:581-97 (1991)	
C72	Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. I):S93 (2002)	
C73	Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," <i>Bio/Technology</i> , Vol. 12:1134-1136 (1994)	
C74	MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor α : in vitro and vivo application" <i>Cytokine</i> , 2(3):162-69 (1990)	
C75	Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i> , Vol. 5:450-456 (1995)	
C76	Osbourm, Jane et al., "From rodent reagents to human therapeutics using antibody guided selection," <i>Methods</i> , Vol. 36:61-68 (2005)	
C77	Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," <i>Ann. Intern. Med.</i> , Vol. 131:768-774 (1999)	
C78	Queen, Cary et al., "A humanized antibody that binds to the interleukin 2 receptor," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 86:10029-10033 (1989)	
C79	Rau, Rolf et al., "Long-term efficacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 41(Suppl.):S55, No. 137 (1998)	
C80	Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i> , Vol. 25:83-88 (2000)	√
C81	Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S55 (2002)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	7	of	10	Attorney Docket Number	BBI-8187RCE

C82	Rau, R. et al., "Combination therapy with the human anti-TNF antibody D2E7 and methotrexate in active chronic polyarthritis," <i>Z. Rheumatol.</i> , Vol. 58(Suppl. 1):1/35, F20 (1999)	✓
C83	Rau, R., "Experiments with D2E7," <i>Z. Rheumatol.</i> , Vol. 58(Suppl. 1):1/21, S51 (1999)	✓
C84	Rau, R. et al., "Effect and compatibility of repeated intravenous doses of the human anti-TNF antibody D2E7 in patients with chronic polyarthritis," <i>Z. Rheumatol.</i> , Vol. 58(Suppl. 1):1/41, P12 (1999)	✓
C85	Rau, R. et al., "Treatment with Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, Slows Radiographic Disease Progression in Rheumatoid Arthritis: Results of a 12-Month Study," <i>J. Clin. Rheum.</i> , Vol. 8(Suppl.):S78 (2002)	
C86	Rau, R. et al., "Adalimumab Inhibits Radiographic Disease Progression in Long-Standing, Rapidly Progressive Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):191 (2003)	
C87	Rau, R., "Adalimumab (a fully human anti-tumour necrosis factor α monoclonal antibody) in the treatment of active rheumatoid arthritis: the initial results of five trials," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. II):ii70-ii73 (2002)	
C88	Rau, R. et al., "Long-term Treatment with the Fully Human Anti-TNF-Antibody D2E7 Slows Radio-graphic Disease Progression in Rheumatoid Arthritis," <i>Arthritis and Rheumatism</i> , Vol. 42(9):S400 (1999)	
C89	Reinhart, Konrad et al., "Assessment of the safety and efficacy of the monoclonal anti-tumor necrosis factor antibody-fragment, MAK 195F, in patients with sepsis and septic shock: A multicenter, randomized, placebo-controlled, dose-ranging study," <i>Crit. Care. Med.</i> , Vol. 24(5):733-742 (1996)	
C90	Revicki, D. et al., "Treatment with Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Improves Physical Function, Vitality, and Mental Health While Reducing Bodily Pain in Patients with Active Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S537 (2002)	
C91	Riechmann, Lutz et al., "Phage Display and Selection of a Site-Directed Randomized Single-Chain Antibody Fv Fragment for Its Affinity Improvement," <i>Biochemistry</i> , Vol. 32:8848-8855 (1993)	
C92	Rudikoff, Stuart et al., "Single amino acid substitution altering antigen-binding specificity," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 79:1979-1983 (1982)	
C93	Salfeld, J. et al., "Generation of Fully Human Anti-TNF Antibody D2E7," <i>Arthritis Rheum.</i> , Vol. 41(9 Suppl.):S57 (1998)	
C94	Sandborn, William J. et al., "Infliximab in the Treatment of Crohn's Disease: A User's Guide for Clinicians," <i>The American Journal of Gastroenterology</i> , Vol. 97(12):2962-2972 (2002)	
C95	Santora, L.C. et al., "Characterization of Noncovalent Complexes of Recombinant Human Monoclonal Antibody and Antigen Using Carbon Exchange, Size Exclusion Chromatography, and BIAcore," <i>Analytical Biochemistry</i> , Vol. 299(2):119-129 (2001)	
C96	Santora, L.C. et al., "Characterization of Recombinant Human Monoclonal Tissue Necrosis Factor- α Antibody Using Cation-Exchange HPLC and Capillary Isoelectric Focusing," <i>Analytical Biochemistry</i> , Vol. 275:98-108 (1999)	
C97	Schattenkirchner, M. et al., "Long-term Use of the Fully Human Anti-TNF Antibody D2E7 in Combination with Methotrexate in Active Rheumatoid Arthritis," <i>Presented at: The Annual Meeting of the European League Against Rheumatism</i> , pg. S228 (2000)	
C98	Schattenkirchner, M. et al., "Long-term Use of the Fully Human Anti-TNF Antibody Adalimumab (D2E7) in Dmard-refractory Rheumatoid Arthritis," <i>Presented at: The Annual Meeting of the European League Against Rheumatism (EULAR)</i> , Prague, Czech Republic, June 2001	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	8	of	10	Attorney Docket Number	BBI-8187RCE

C99	Schattenkirchner, M. et al., "Phase 1 study on the effectiveness and compatibility of weekly subcutaneous injections of the human anti-TNF antibody D2E7 in chronic polyarthritis," <i>Z. Rheumatol.</i> , Vol. 58(Suppl. 1):1/42, P14 (1999)	√
C100	Schattenkirchner, M. et al., "Efficacy and Tolerability of Weekly Subcutaneous Injections of the Fully Human Anti-TNF-Antibody D2E7 in Patients with Rheumatoid Arthritis - Results of a Phase I Study," <i>Arthritis and Rheumatism</i> , Vol. 41(9):S57 (1998)	
C101	Schiff, M. et al., "Rates of Infection in Adalimumab Rheumatoid Arthritis Clinical Trials," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):184 (2003)	
C102	Schiff, M. et al., "A Randomized, Controlled, Safety Trial of Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Given to RA Patients in Combination with Standard Rheumatologic Care: The STAR (Safety Trial of Adalimumab in Rheumatoid Arthritis) Trial," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S169 (2002)	
C103	Schiff, Michael H. et al., "Sustained Efficacy of Adalimumab (HUMIRA™) Plus Methotrexate in Rheumatoid Arthritis (RA) Patients," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S314 (2003)	
C104	Sibilia, Jean, "Combinaison de traitements de fond dans la polyarthrite rhumatoïde," <i>Ann. Med. Interne.</i> , Vol. 153(1):41-52 (2002)	√
C105	Strand, V. et al., "Treatment with Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Improves Physical Function and Health Related Quality of Life (HRQOL) in Patients with Active Rheumatoid Arthritis (RA)," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S175 (2002)	
C106	The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, "Inflammatory Bowel Diseases," Mark H. Beers Ed., Merck Research Laboratories, pgs. 302-313 (1999)	
C107	Thomas, Clayton L., Taber's Cyclopedic Medical Dictionary, F.A. Davis Company, pgs. 118-119 (1977)	
C108	Thompson, Julia et al., "Affinity Maturation of a High-affinity Human Monoclonal Antibody Against the Third Hypervariable Loop of Human Immunodeficiency Virus: Use of Phase Display to Improve Affinity and Broaden Strain Reactivity," <i>J. Mol. Biol.</i> , Vol. 256:77-88 (1996)	
C109	Tomlinson, Ian M. et al., "The Repertoire of Human Germline V _H Sequences Reveals about Fifty Groups of V _H Segments with Different Hypervariable Loops," <i>J. Mol. Biol.</i> , Vol. 227:776-798 (1992)	
C110	Tomlinson, Ian M. et al., "The structural repertoire of the human V _K domain," <i>The EMBO Journal</i> , Vol. 14(18):4628-4638 (1995)	
C111	Tracey, Kevin J. et al., "Tumor Necrosis Factor: A Pleiotropic Cytokine and Therapeutic Target," <i>Annu. Rev. Med.</i> , Vol. 45:491-503 (1994)	
C112	Vajdos, Felix F. et al., "Comprehensive Functional Maps of the Antigen-binding Site of an Anti-ErbB2 Antibody Obtained with Shotgun Scanning Mutagenesis," <i>J. Mol. Biol.</i> , Vol. 320:415-428 (2002)	
C113	van de Putte, L.B.A. et al., "One Year Efficacy Results of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 43(9 Suppl.):S269 (2000)	
C114	Van De Putte, L.B. et al., "Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in the Treatment of Patients with Rheumatoid Arthritis Who Failed Previous DMARD Therapy: Efficacy and Safety Results from a 6-Month Phase III Study," <i>JCR: Journal of Clinical Rheumatology</i> , Vol. 8(Suppl. 3):S89 (2002)	
C115	Van de Putte, Atkins Malaise et al., "Adalimumab (D2E7) Monotherapy in the Treatment of Patients with Severely Active Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S171 (2002)	
C116	van de Putte, B.A. et al., "Efficacy of the Fully Human anti-TNF Antibody D2E7 in Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 42(9):S400, No. 1977 (1999)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	9	of	10	Attorney Docket Number	BBI-8187RCE

C117	van de Putte, L.B.A. et al., "A placebo-controlled phase 1 study of the human anti-TNP-antibody D2E7 in patients with active chronic polyarthritis," <i>Z. Rheumatol.</i> , Vol. 58(Suppl. 1):1/34, F19 (1999)	√
C118	Van de Putte, L.B.A. et al., "Efficacy and Safety of Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Patients with Rheumatoid Arthritis Who Failed Previous DMARD Therapy: 6-Month Results from a Phase III Study," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S168 (2002)	
C119	van de Putte, Leo, et al., "Adalimumab," TNF α -Inhibition in the Treatment of Rheumatoid Arthritis, MD Martin Dunitz, Larry W. Moreland, Ed., pgs. 71-93 (2003)	
C120	van de Putte, L.B.A. et al., "Sustained 5-Year Efficacy of Adalimumab (HUMIRA™) Monotherapy in DMARD-Refractory rheumatoid arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S314 (2003)	
C121	van de Putte, L.B.A. et al., "Efficacy and safety of the fully human anti-tumour necrosis factor α monoclonal antibody adalimumab (D2E7) in DMARD refractory patients with rheumatoid arthritis: a 12 week, phase II study," <i>Ann. Rheum. Dis.</i> , Vol. 62:1168-1177 (2003)	
C122	Van de Putte, Leo B.A. et al., "A Single Dose Placebo Controlled Phase I Study of the Fully Human Anti-TNF Antibody D2E7 in Patients with Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 41:S57 (1998)	
C123	van der Poll, T. et al., "Effect of postponed treatment with an anti-tumour necrosis factor (TNF) F(ab') ₂ fragment on endotoxin-induced cytokine and neutrophil responses in chimpanzees," <i>Clin. Exp. Immunol.</i> , Vol. 100:21-25 (1995)	
C124	van Riel, P.L.C. et al., "Long-Term Treatment with Adalimumab (D2E7) Using Background Methotrexate in Active Rheumatoid Arthritis: Results of a 3 Year Study," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S534 (2002)	
C125	Vaughan, Tristan J. et al., "Human antibodies by design," <i>Nature Biotechnology</i> , Vol. 16:535-539 (1998)	
C126	Velagapudi, R.B. et al., "Pharmacokinetics of Adalimumab (D2E7), a Fully Human Anti-TNF- α Monoclonal Antibody, Following a Single Intravenous Injection in Rheumatoid Arthritis Patients Treated with Methotrexate," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S133 (2002)	
C127	Velagapudi, Raja B. et al., "Effect of Methotrexate (MTX) Coadministration on the Pharmacokinetics (PK) of Adalimumab (HUMIRA™, Abbott) Following a Single Intravenous (iv) Injection," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S141 (2003)	
C128	Ward, E. Sally et al., "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>Escherichia coli</i> ," <i>Nature</i> , Vol. 341:544-546 (1989)	
C129	Weinblatt, M. et al., "The ARMADA Trial: Efficacy and Safety of Adalimumab in Patients with Active RA at 24 Months," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):98 (2003)	
C130	Weinblatt, Michael E. et al., "The ARMADA Trial: Sustained Improvement and Tolerability in Long-Term Follow-Up of Patients Treated with Adalimumab (HUMIRA™)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S314 (2003)	
C131	Weinblatt, Michael E. et al., "Adalimumab, a Fully Human Anti-Tumor Necrosis Factor α Monoclonal Antibody, for the Treatment of Rheumatoid Arthritis in Patients Taking Concomitant Methotrexate," <i>Arthritis & Rheumatism</i> , Vol. 48(1):35-45 (2003)	
C132	Weisman, Michael et al., "A Dose Escalation Study Designed to Demonstrate the Safety, Tolerability and Efficacy of the Fully Human Anti-TNF Antibody, D2E7, Given in Combination with Methotrexate," <i>Arthritis Rheum.</i> , Vol. 43(9 Suppl.):S391 (2000)	
C133	Weisman, Michael H. et al., "Efficacy, Pharmacokinetic, and Safety Assessment of Adalimumab, a Fully Human Anti-Tumor Necrosis Factor-Alpha Monoclonal Antibody, in Adults with Rheumatoid Arthritis Receiving Concomitant Methotrexate: A Pilot Study," <i>Clinical Therapeutics</i> , Vol. 25(6):1700-1721 (2003)	

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/622932-Conf. #3572
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis BANERJEE
				Art Unit	1643
				Examiner Name	D. J. Blanchard
Sheet	10	of	10	Attorney Docket Number	BBI-8187RCE

	C134	Wellborne, F. et al., "Adalimumab (D2E7), a Fully Human Anti-TNF- α Monoclonal Antibody, Improved Health-Related Quality of Life in Patients with Active Rheumatoid Arthritis Despite Concomitant Methotrexate Therapy," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S518 (2002)	
	C135	Wells, A.F. et al., "Incidence of Injection-Site Reactions Associated with Adalimumab (D2E7) Give Subcutaneously for at Least 6 Months: A Retrospective Analysis of 4 Phase II/III Clinical Trials," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S171 (2002)	
	C136	Wells, A.F. et al., "Injection-site Reactions in Adalimumab Rheumatoid Arthritis (RA) Pivotal Clinical Trials," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):411 (2003)	
	C137	Wiendl, Heinz et al., "Therapeutic Approaches in Multiple Sclerosis, Lessons from Failed and Interrupted Treatment Trials," <i>Biodrugs</i> , Vol. 16(3):183-200 (2002)	
	C138	Winter, Greg et al., "Making Antibodies by Phage Display Technology," <i>Annu. Rev. Immunol.</i> , Vol. 12:433-455 (1994)	
	C139	Winter, Greg et al., "Humanized antibodies," <i>Immunology Today</i> , Vol. 14(6):243-246 (1993)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.